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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,807	12/16/2003	Jay Miazga	000309-00261	2864

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT PAPER NUMBER

3762

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/735,807

Applicant(s)

MIAZGA ET AL.

Examiner

George R. Evanisko

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 and 10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date: _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/16/06, 4/28/04</u>  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of the restriction and election in the reply filed on 6/26/06 is acknowledged.

### ***Information Disclosure Statement***

The information disclosure statement filed 4/28/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein for the lined through references have not been considered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, in the next to last line and last line, "to removably receive...at least part of the second segment in contact with the electrically conductive portion" is vague and seems to be missing several words. It is suggested to either delete "in contact...portion" or insert language similar to claim 6.

In claims 5 and 7, the claims are vague since it is unclear in what direction, axis, and/or orientation “spaced apart” is considered to be less or more when relating one configuration to the other.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofmann (6208893). Hofman shows in figures 21 and 22 (and figures 24-26) the device having needle electrodes 152 that are resilient since they are bent before they are pushed through the sockets of the circuit board (figure 21, around the area where reference numeral 146 is located) and are straight (figure 22) after they are pushed through the sockets. In addition, Hofman describes the claimed coupling member as the metal sockets, 116 and figure 11, and having a diameter smaller than the distance between the first end/segment of the needle (the area where the needle points, such as at numeral 152) and the second end/segment of the needle (such as at the area right above numeral 146). In addition, Hofman shows in figures 21 and 22 the needles offset and at a 180 degree bend (i.e. straight after the offset). Hofman also shows in figures 24 and 25 one needle, 178, connected to pulse generator and metal socket, also being offset and having a 180 degree bend. Hofman shows in figures 21 and 22, the housing, 154 or 146, with attachment device, 148. It is noted that element 148 is capable of meeting the functional use recitation of releasably coupleable to a recipients skin since the device can be placed on and off of the skin.

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Regarding claims 5 and 7, the device is spaced apart less in one configuration versus the other (shown in figures 21 and 22 or 24 and 25), since if you hold the first segment and second segment points at the same location along the needle in figures 21 and 22, taking the curve out of the needle will result is a different amount of space (less or more) between those first and second segment points. Finally, the device is a percutaneous apparatus/electrode since it is capable of being used through skin and to areas located through the skin (column 5, lines 46-55).

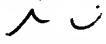
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
George R Evanisko  
Primary Examiner  
Art Unit 3762

GRE  
9/9/06

9/10/06